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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,963	06/28/2002	Erwin Bischoff	Le A 33 965	4889

27941 7590 05/19/2004

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,963	BISCHOFF ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10 and 12-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-10 and 12-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on March 8, 2004 have been received and entered into the application.

Action Summary

The rejection of claims 18 and 19 of record under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicants' amendment.

Claims 1, 5, 7-10, 12-18 and 20-26 of record rejected under 35 U.S.C. 103 (a) over Liao et al. (U.S.Patent No. 6,147,109) in view of Niewohner et al. (WO 99/24433) of record is maintained for the reasons stated in the previous office action.

Claims 6 and 19 of record rejected under 35 U.S.C. 103 (a) over Liao et al. (U.S.Patent No. 6,147,109) in view of Niewohner et al. (WO 99/24433) of record and further in view of Doherty, Jr. et al. (U.S.Patent No. 6,037,346) is maintained for the reasons stated in the previous office action.

Claims 1,5,7-10 and 12-18, 20-26 of record rejected under 35 U.S.C. 103 (a) over Liao et al. (U.S.Patent No. 6,147,109) in view of R&D Drug News (1998) is maintained for the reasons stated in the previous office action.

Claims 6, 19 of record rejected under 35 U.S.C. 103 (a) over Liao et al. (U.S.Patent No. 6,147,109) in view of R&D Drug News (1998) in view of R&D Drug

News (1998) and further in view of Doherty, Jr. et al. (U.S.Patent No. 6,037,346) is maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed March 8, 2004 have been fully considered but they are not persuasive. Applicants argue that there is no suggestion to one of ordinary skill in the art that by combining an HMG-CoA reductase inhibitor with one of these pharmaceutical agents since the failure rate in drug development is extremely high and the toxicity or an adverse event is observed during the development of a therapeutic.

This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is clear motivation for combining the components flows from their individually known common utility for treating erectile dysfunction (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Therefore it would be expected that the combination of components would treat erectile dysfunction as well. Further to address the argument that failure rate in drug development is extremely high and the toxicity or an adverse event is observed during the development of a therapeutic. This is not persuasive because this is a bold allegation not specified to the each specific active agent at issue.

Moreover, Applicants have not supply why one of ordinary skill in the art would not combine specific active agents at issue without specific data showing the toxic reaction from combining these two specific agents. Applicants further argue that the categories of pharmaceutical agents are very broad, for example, and "amino acid" or an "inhibitor" therefore one skilled in the art would not be motivated to combine an HMG-CoA reductase inhibitor with an amino acid or an inhibitor with the expectation of successful treatment of any disorder. This is not persuasive because each of the HMG-CoA reductase inhibitor to be employed and their useful effect for the treatment of impotence is taught by Liao et al. and that any other agents that adjunct the treatment of impotence can be simultaneously employed is also taught by Liao et al. Therefore, absent any evidence to contrary there would have been a reasonable expectation of successfully treating sexual dysfunction by combining HMG-CoA reductase and Vardenafil, which are individually known to have same effect as taught by the prior art to achieve at least an additive effect. Applicants next argue that Doherty et al. mentions additional active agents but there is no suggestion to combine PDE inhibitors with HMG-CoA reductase inhibitors. This is not persuasive because Doherty et al. teach the kit for the erectile dysfunction comprising PDE inhibitors as other active agents are well-known in the art. Therefore it would have been obvious to formulate the Liao et al's composition as modified by Niewohner et al. in a kit since PDE inhibitors with other active agents for the treatment of erectile dysfunction in a kit is old and well-known. One would have been motivated to formulate the combination of HMG-CoA reductase and Vardenafil in a kit for the convenience of having the agents in one package. Applicants argue R& D Drug

News discloses vardenafil; however, R & D Drug News does not teach or suggest the combination of vardenafil and HMG-CoA reductase inhibitors and there is no motivation on the disclosure of R& D Drug News to combine vardenafil and HMG-CoA reductase inhibitors. This is not persuasive because R & D Drug News teaches vardenafil is the phosphodiesterase inhibitor and it has a potential therapy for the erectile dysfunction. This teaching is a clear motivation for combining the components flows from their individually known common utility for treating erectile dysfunction (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Applicants lastly argue that Liao, et al, R & D Drug News and Doherty et al. fail to teach or suggest the invention as presently claimed. This is not persuasive because Liao et al. teach HMG-CoA reductase inhibitors are useful for the treatment of impotence and it can be combined with other active agents with same effect. R & D reference teaches vardenafil can be use for the very same effect, Doherty et al. teach that "kit" is well-known in the pharmaceutical art comprising PDE inhibitors for the erectile dysfunction therapy. As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been prima facie obvious to combine HMG-CoA reductase inhibitor and vardenafil cojointly in a (kit) formulation to treat erectile dysfunction. Thus,

the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of December 5, 2003 is deemed proper and asserted with full force and repeated to obviate applicants' claims.

None of the claims are allowed.

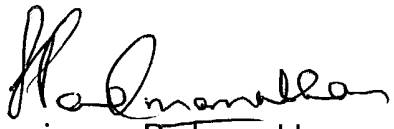
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
May 6, 2004